REMARKS

Claims 1, 4 and 7-9 are pending in the application. The rejection of claims 1, 4, 7 and 9 were affirmed by the Board of Patent Appeals & Interferences ("the Board") in *Ex parte Phipps*, Appeal No. 2007-1556, decided on June 27, 2008. Because, as discussed below, the Board raised a new ground of rejection in its decision, Applicants are requesting reconsideration by the Examiner of all claim rejections pursuant to 37 C.F.R. § 41.50(b)(1). In accordance with that provision, Applicants are herewith submitting an "appropriate amendment" to the claims. Specifically, claim 1 has been amended to specify that the analgesic drug (a fentanyl salt) delivery period is 24 hours and about 10-100 doses of the analgesic drug are delivered over the total delivery period. Support for the amendment can be found throughout the specification and claims as originally filed, *e.g.*, page 18, lines 8-11.

Claims 1, 4 and 7-9 are presented for further proceedings. Reconsideration of the claim objections and rejections and allowance of the pending claims in view of the amendment above and following remarks are respectfully requested.

New Ground of Double-Patenting Rejection

In the Examiner's Answer, the Examiner maintained the rejection of claims 1, 4 and 7-9 under the judicially created doctrine of double-patenting as obvious over claims 1-9 of Southam (US 6,171,294). According to the Examiner, although the claims are not identical, they are not patentably distinct because instant claim 1 recites a method of drug delivery where the concentration is maintained above about 16 mM, which from Applicants' specification is a composition that comprises about 1-2% fentanyl, which is

also the same amount recited in claim 7 of Southam. Thus, according to the Examiner, instant claim 1 is merely a broader version of claim 1 of Southam.

In its decision, the Board affirmed the Examiner's double-patenting rejection of claims 1, 4 and 7-9 as obvious over the claims of Southam. However, the Board did not base its decision of the Examiner's position, namely that instant claim 1 is a broader version of claim 1 of Southam, but rather because claim 1 does not state a delivery period. According to the Board, "Claim 1 of Southam has an upper limit for a delivery period, but not a lower limit; patented claim 2 is directed to a delivery period of about 5 to 15 minutes. Thus, when the concentration in the Southam delivery device is above 16 mM for 5 minutes – all the limitations of claim instant 1 [sic] are met."

Thus, although not styled as such, the Board's affirmance rested on an entirely new basis for double-patenting. The Examiner's reliance on the "broadness" of instant claim 1 compared to claim 1 of Southam is clearly distinct from the Board's reliance on the delivery period of 5 to 15 minutes in claim 2 of Southam. Applicants respectfully request that they be provided a "fair opportunity to react to the thrust of the rejection" made in the Board Decision. *In re Kronig*, 539 F.2d 1300, 1302 (CCPA 1976). Fundamental fairness, embodied in 37 C.F.R. § 41.50(b), dictates that Applicants be given an opportunity to respond to this new ground of rejection. *See In re Kumar*, 418 F.3d 1361, 1367 (Fed. Cir. 2005) ("In calculating the overlapping values, the Board found facts not found by the examiner regarding the differences between the prior art and the claimed invention, which in fairness required an opportunity for response."); *In re Waymouth*, 486 F.2d 1058, 1060-61 (CCPA 1974) ("Although the same phrase ('sodium iodide . . . present in amount of at least 0.17 mg./cc of arc tube volume') was questioned

by both the examiner and the board, the bases of their rejections were wholly different, necessitating different responses by appellants. To attempt to deny appellants an opportunity to provide a different and appropriate response to the board's rejection by saying that the board merely advanced 'an additional reason' for affirming the examiner begs the question and does not satisfy . . . administrative due process . . . ."); *In re Echerd*, 471 F.2d 632, 635 (CCPA 1973) ("We find the new reliance by the board on Gouveia alone to be in effect a new ground of rejection. New portions of the reference are relied upon to support an entirely new theory and the statutory basis appears to have been shifted to 35 USC 102. Under such circumstances, appellants should have been accorded an opportunity to present rebuttal evidence as to the new assumptions of inherent characteristics made by the board."); *In re Moore*, 444 F.2d 572, 574-75 (CCPA 1971) (The Board of Appeals sustained the examiner on the point that a declaration asserting that a reference did not make a utility for a disclosed compound was deficient but then went further and held the affidavit deficient on the alternative ground that the reference disclosure did make a utility for the claimed compound obvious. The Court stated, "[a] finding such as was made here, however, supporting as it does an alternative ground for sustaining the examiner's rejection, and apparently based on nothing more than a bare allegation of scientific fact, does everything but cry out for an opportunity to respond.").

Taking this opportunity pursuant to 37 C.F.R. § 41.50(b)(1), Applicants have amended claim 1 to specify that the analgesic drug (a fentanyl salt) delivery period is 24 hours and about 10-100 doses of the analgesic drug are delivered over the total delivery period. The Board's affirmance of the double-patenting rejection was based on the

absence of a delivery period in instant claim 1, which led to a finding of obviousness over the 5 to 15 minute delivery period of claim 2 of Southam. However, neither the Board nor the Examiner has pointed to any evidence that the concentration of fentanyl salt in the delivery device of claims 1, 2, 3, 6 and 7 of Southam would remain above 16 mM following 10-100 dose administrations over an entire ***24 hour period***, as recited in instant claim 1.

Accordingly, Applicants submit that claim 1 as amended (and thus claims 4 and 7-9 dependent therefrom) is patentable over claims 1, 2, 3, 6 and 7 of Southam, and reconsideration of this basis for rejection is respectfully requested.

Additional Prior Art Rejections

Pursuant to MPEP § 1214.01, Applicants submit that the amendment to claim 1 overcomes the remaining prior art rejections affirmed by the Board. As stated in MPEP § 1214.01: "Prosecution before the examiner of the 37 CFR 41.50(b) rejection can incidentally result in overcoming the affirmed rejection even though the affirmed rejection is not open to further prosecution. Therefore, it is possible for the application to be allowed as a result of the limited prosecution before the examiner of the 37 CFR *> 41.50(b) rejection." As such, Applicants respectfully request that the Examiner withdraw all the remaining claim rejections, and allow the application to pass to issuance.

1. Obviousness Over Phipps '739

The Board affirmed the rejection of claims 1, 4 and 7-9 under 35 U.S.C. § 103(a) as obvious over Phipps '739 (US 5,423,739) in view of Rebinder (Chapter 12, Iontophoresis, in *Electrokinetischeskie kapillarnykh system*, 1956), Phipps '894 (US

5,125,894) and Muller (US 5,320,731). The Board agreed with the Examiner that the claimed amount of 16 mM fentanyl salt would have been routinely determined based on the suggestion in the prior art that a threshold drug concentration is necessary to eliminate the effects of competing parasitical ions.

Although still disagreeing with Examiner and the Board, Applicants submit that amending claim 1 to specify that the 16 mM concentration of fentanyl salt must be maintained following 10-100 dose administrations during the entire 24 hour delivery period renders the claims patentable over the combination of Phipps '739, Rebinder, Phipps '894 and Muller. Although the Examiner and Board contend that ***starting*** with 16 mM fentanyl salt is routine, neither has pointed to any evidence that the cited references teach or suggest that the concentration of fentanyl salt should be 16 mM ***following administration of the final dose at the end of the 24 hour delivery period***. Only Applicants' application discloses such a concept.

Accordingly, Applicants submit that claim 1 as amended (and thus claims 4 and 7-9 dependent therefrom) is patentable over Phipps '739 in view of Rebinder, Phipps '894 and Muller, and reconsideration of this basis for rejection is respectfully requested.

2. Anticipation and Obviousness Over Haak

The Board affirmed the rejection of claims 1, 4 and 7-9 under 35 U.S.C. § 102(b) as anticipated by Haak (US 5,203,768), or in the alternative, under 35 U.S.C. § 103(a) as obvious over Haak in view of Rebinder, Phipps '894 and Muller, or in view of Newman (US 4,931,046). The Board agreed with the Examiner that Haak describes a drug delivery device that meets all the limitations of the claims. The Board discounted Applicants' argument that there is nothing to dispute the possibility that the device of

Haak can be operated for a substantial period of time until the drug reservoir is depleted, stating that instant claim 1 does not positively recite the delivery period's duration. Thus, according the Board, the limitation "maintained substantially throughout the total analgesic drug iontophoretic delivery period" in claim 1 is met by one on-off cycle of the device in Haak.

Although still disagreeing with Examiner and the Board, Applicants submit that amending claim 1 to specify that the 16 mM concentration of fentanyl salt must be maintained following 10-100 dose administrations during the entire 24 hour delivery period renders the claims patentable over Haak alone, or in combination with Rebinder, Phipps '894 and Muller, or Newman. The amendment directly addresses the issue raised by the Board, namely that the claim 1 does not positively recite the delivery period's duration. Clearly, the newly recited delivery period duration of ***24 hours*** is not met by one on-off cycle of the device in Haak, nor is it fairly suggested by the device in Haak.

3. Obviousness Over Theeuwes

The Board affirmed the rejection of claims 1, 4 and 7-9 under 35 U.S.C. § 103(a) as obvious over Theeuwes (US 5,232,438) in view of Rebinder, Phipps '894 and Muller. The Board agreed with the Examiner that Theeuwes in view of Rebinder, Phipps '894 and Muller suggested the claimed invention for the same reasons as given for Phipps '739 in combination with the same secondary references.

As with Phipps '739, Applicants submit that amending claim 1 to specify that the 16 mM concentration of fentanyl salt must be maintained following 10-100 dose administrations during the entire 24 hour delivery period renders the claims patentable over the combination of Theeuwes, Rebinder, Phipps '894 and Muller. Again, although

the Examiner and Board contend that ***starting*** with 16 mM fentanyl salt is routine, neither has pointed to any evidence that the cited references teach or suggest that the concentration of fentanyl salt should be 16 mM ***following administration of the final dose at the end of the 24 hour delivery period***. Only Applicants' application discloses such a concept.

Accordingly, Applicants submit that claim 1 as amended (and thus claims 4 and 7-9 dependent therefrom) is patentable over Theeuwes in view of Rebinder, Phipps '894 and Muller, or Newman, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 1, 4 and 7-9 are now in condition for allowance, early notice of which would be appreciated. No additional fees are believed due at this time. If, however, any additional fees are due, the Commissioner is authorized to charge any such fee to our Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

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Respectfully submitted,

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